K050101

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

APR 15 2005 ***The Trabecular Metal Osteonecrosis Intervention Implant***

Submitter Name	Zimmer Trabecular Metal Technology, Inc.
And Address:	80 Commerce Drive Allendale, New Jersey 07401-1600
Contact Person:	Robert A Poggie, PhD
Phone Number:	(201) 818 - 1800, X 519
Fax Number:	(973) 829 - 0825
Date Prepared:	April 12, 2005
Device Trade Name:	Trabecular Metal Osteonecrosis Intervention Implant
Device Common Name:	Porous metal rod
Classification Number and Name:	21 CFR § 888.3030; product code HRS - Single/multiple component metallic bone fixation appliances and accessories

Substantial Equivalence:

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

Device Description:

The *Trabecular Metal Osteonecrosis Intervention Implant* is fabricated from Trabecular Metal™ porous tantalum. The implant is cylindrical in shape with a 10 mm diameter and length options from 70 to 130 mm in 5 mm increments.

The *Trabecular Metal Osteonecrosis Intervention Implant* possesses distal threads for engagement of bone. The threaded portion is 25 mm in length and the outer diameter is 14 mm, the inner diameter is 10 mm. Slots within the lateral most aspect of the implant interface with the driving instrument.

MATERIALS: Tantalum (Trabecular Metal™).

510(k) Summary Continued...

Indications for Use:

The Trabecular Metal Osteonecrosis Intervention Implant is indicated for use in patients with Stage I or Stage II osteonecrosis of the femoral head (Steinberg/UPenn System) and who would qualify for core decompression based upon physical and radiographic examination and medical history. The Trabecular Metal Osteonecrosis Intervention Implant may be used with or without bone graft.

Device Technological Characteristics & Comparison to Predicate Device:

A comparison of device technological characteristics and properties demonstrates that the device is substantial equivalent to the cited predicate devices.

Performance Data:

The *Trabecular Metal Osteonecrosis Intervention Implant* was characterized per modified ASTM testing standards for THR devices, mechanical test methods that simulated bone deficiencies caused by early stage femoral head osteonecrosis, and finite element modeling of the device. The results of these tests showed that the subject device safely supports weakened bone associated with early stage osteonecrosis of the femoral head. The clinical data collected under IDE G990234 show the device to perform safely and efficaciously per the indications for use.

Conclusion:

The *Trabecular Metal Osteonecrosis Intervention Implant* is substantially equivalent to the cited predicate devices identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 15 2005

Robert A. Poggie, Ph.D.
Zimmer Trabecular Metal Technology, Inc.
80 Commerce Drive
Allendale, New Jersey 07401-1600

Re: K050101
Trade/Device Name: The Trabecular Metal Osteonecrosis Intervention Implant
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/ multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: January 17, 2005
Received: January 18, 2005

Dear Dr. Poggie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

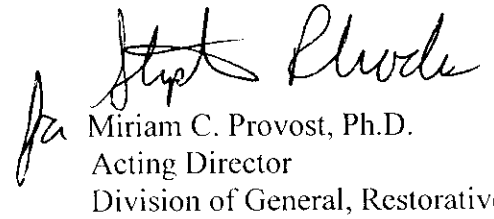
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): **K050101**

Device Name: **The Trabecular Metal Osteonecrosis Intervention Implant**

Indications For Use:

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Prescription Use	X	AND/OR...	Over-The-Counter Use	

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K050101